Decision on Plan B Called Very Unusual

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A long-awaited report on the 2004 Food and Drug Administration decision to reject an application to allow easier access to the "morning after pill" concludes that the decision was highly unusual, was made with atypical involvement from top agency officials, and may well have been made months before it was formally announced.

The draft report by the Government Accountability Office, requested by Congress in the summer of 2004, is to be finalized and made public by the end of the month. But some congressional staffers have been briefed on its conclusions in recent weeks, and some were allowed yesterday to read the findings.

As described by some familiar with the draft, the GAO found that top FDA officials participated in assessing the application to allow the emergency contraceptive Plan B to be sold without a prescription, and that such unusual high-level involvement was justified by the perceived sensitivity of the issue.

Critics of the FDA's May 2004 decision, and of a subsequent postponing of any decision making this August, have accused the agency of giving in to political pressure from social conservatives opposed to the application. While an FDA advisory panel overwhelmingly supported the proposal in late 2003 on scientific grounds and the agency's medical reviewers were similarly convinced it should be approved, the agency's top leaders have said it could not be approved because of outstanding questions about whether it should be available to young girls, and if not, how to keep it from them.

When Steven Galson, then-acting director of the Center for Drug Evaluation and Research, announced the rejection, he said the decision was his own, had been recently made and was based on scientific concerns. The GAO report, however, indicates the decision was solidified months earlier and that other top officials were involved in the decision.

The 2004 decision was announced when then-acting Commissioner Lester M. Crawford was in charge, having taken over for Commissioner Mark McClellan in March. Crawford resigned with little explanation last month, only two months after being confirmed by the Senate following a heated battle over the Plan B application.

The draft GAO report indicates that Galson voiced concerns in FDA meetings about how easier availability of Plan B would effect sexual behavior by girls.

Plan B consists of the high dose of a common contraceptive, and can prevent pregnancy if taken within 72 hours of having unprotected sex. The FDA does not consider the drug to cause an abortion, but some religious groups believe that under some circumstances it can cause a fertilized egg to die.